NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OYSTER POINT PHARMA, INC., Plaintiff, v. APOTEX INC., Defendant.	**Civil Action No. 23-3860 (SRC)** **OPINION & ORDER**

CHESLER, U.S.D.J.

This matter comes before the Court on the application for supplemental claim construction by Plaintiff Oyster Point Pharma, Inc. ("Oyster Point") and Defendant Apotex, Inc. ("Apotex"). In brief, at a conference on June 4, 2025, the Court directed the parties to submit an additional question of claim construction to the Court for decision, limiting the parties to one set of briefs of no more than five pages each. Having considered the briefs and, for the reasons that follow, the Court construes "varenicline" in the patents at issue to include both its free-base form and its salt form.

This case arises from patent infringement litigation involving five patents generally directed to treatment methods with the drug varenicline: U.S. Patent Nos. 9,597,284 ("the '284 patent"), 10,456,396 ("the '396 patent"), 11,903,941 ("the '941 patent"), 11,903,943 ("the '943 patent"), and 11,911,380 ("the '380 patent"). Plaintiff Oyster Point owns these patents and has sued the Defendant for patent infringement under the Hatch-Waxman Act. The parties seek claim construction of one term in these patents, "varenicline."

ANALYSIS

I. The law of claim construction

A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). "[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law." Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

The focus of claim construction is the claim language itself:

> It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

> We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.
> The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .
>
> In some cases, the ordinary meaning of claim language as understood by a person

> of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. Claim construction of "varenicline"

The Court is required to resolve a claim construction dispute. The parties appear to agree that their dispute has its origins in their earlier agreement about the construction of the claim term, "varenicline:"

> **Plain and ordinary meaning, which is "the compound described by the chemical name: 7,8,9,10-tetrahydro-6,10-methano-6*H*-pyrazino[2,3-h][3]benzazepine, or having the structure:**
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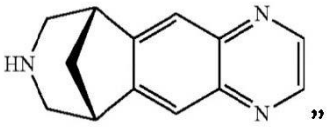
> 
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> "

(Amended Joint Claim Construction and Prehearing Statement at A-2.) While the parties had agreed on this construction, their agreement left an ambiguity which had to be resolved: whether this plain and ordinary meaning limited the term to its free-base form or included pharmaceutically acceptable salt forms. The Court notes that this issue has been festering for some time and, indeed, correspondence in 2024 between counsel, submitted by the parties to the

Court, indicates their uncertainty over this question. Thus, the Court is called upon to resolve this ambiguity through the ordinary means of claim construction, as laid out by the Federal Circuit.[1]

The Court's answer to this question is unequivocal: the term "varenicline" in the claims at issue covers varenicline salts as well as the free-base form because, principally, the common specification clearly states that the scope of the claimed pharmaceutical compositions of nicotinic acetylcholine receptor agonists includes their salts:

> The pharmaceutical compositions will include a nicotinic acetylcholine receptor agonist as described herein as an active ingredient in free-acid or free-base form, or in a pharmaceutically acceptable salt form. In addition, the methods and pharmaceutical formulations described herein include the use of N-oxides (if appropriate), crystalline forms, amorphous phases, as well as active metabolites of these nicotinic acetylcholine receptor agonists having the same type of activity. In some embodiments, the nicotinic acetylcholine receptor agonists described herein may exist in unsolvated form or in solvated forms with pharmaceutically acceptable solvents such as water, ethanol, and the like. The solvated forms of the nicotinic acetylcholine receptor agonists presented herein are also considered to be disclosed herein. In some embodiments, the compounds may exist as tautomers. All tautomers are included within the scope of the nicotinic acetylcholine receptor agonists presented herein.
>
> In some embodiments, the nicotinic acetylcholine receptor agonists exist as enantiomers, diastereomers, or other steroisomeric forms. The nicotinic acetylcholine receptor agonists disclosed herein include all enantiomeric, diastereomeric, and epimeric forms as well as mixtures thereof.

'396 patent, col.87 ll.38-59.

[1] Apotex begins its brief by pointing to the parties' previously agreed-upon definition of "varenicline," asking the Court to "clarify" that definition. At the outset, the Court needs to make clear that today's decision does not attempt to clarify what the parties agreed to when they agreed to their agreed-upon construction. Instead, today's decision construes the claim term "varenicline" as it appears in the claims at issue. This decision addresses only the question of whether, under the Federal Circuit law of claim construction, the claim term, "varenicline," covers varenicline salts in addition to its free-base form.

Presently at issue are ten claims in five patents. In the '284 patent, claims 9 and 14:

> 1. A method of treating dry eye, comprising the local administration of a therapeutically effective amount of a nicotinic acetylcholine receptor agonist into the nasal cavity of an individual in need thereof, wherein the agonist selectively binds to the peripheral nicotinic acetylcholine receptor, is administered in a non-systemically bioavailable dose between 5 micrograms and 50 micrograms per dose, and does not cross the blood-brain barrier in a pharmacologically relevant concentration; and wherein the nicotinic acetylcholine receptor agonist is varenicline.
>
> 9. The method of claim 1, wherein the nicotinic acetylcholine receptor agonist is administered at least twice daily.
>
> 13. The method of claim 1, wherein the trigeminal nerve is activated.
>
> 14. The method of claim 13, wherein the anterior ethmoidal nerve is activated.

In the '396 patent, claims 2 and 74:

> 1. A method of treating dry eye in an individual in need thereof, comprising administering between 5 micrograms and 600 micrograms of varenicline in alternating nostrils of the individual.
>
> 2. The method of claim 1, comprising administering between 5 micrograms and 100 micrograms of varenicline in alternating nostrils of the individual.
>
> 61. A method of increasing tear production in an individual in need thereof, comprising administering between 5 micrograms and 600 micrograms of varenicline in alternating nostrils of the individual.
>
> 74. The method of claim 62, wherein varenicline is administered at least once daily.

In the '941 patent, claim 20:

> 13. A method of treating dry eye in a human, comprising nasally administering between 5 micrograms and 100 micrograms of varenicline twice daily, wherein varenicline is in a liquid pharmaceutical formulation comprising a concentration of varenicline between about 0.1 mg/mL and about 10 mg/mL.
>
> 16. The method of claim 13, comprising nasally administering between 25

micrograms and 100 micrograms of varenicline twice daily.

18. The method of claim 16, wherein the liquid pharmaceutical formulation comprises a concentration of varenicline between 0.5 mg/mL and 1 mg/mL.

19. The method of claim 18, wherein the liquid pharmaceutical formulation is administered as a nasal spray.

20. The method of claim 19, wherein the liquid pharmaceutical formulation does not include a preservative.

In the ’943 patent, claims 19 and 26:

17. A method of increasing tear production in an individual in need thereof comprising administering a therapeutically effective amount of varenicline to the individual, wherein said administration is by locally administering a pharmaceutical formulation comprising varenicline or a pharmaceutically acceptable varenicline salt and one or more pharmaceutically acceptable inactive ingredients, wherein the concentration of varenicline in the formulation is between about 0.1 mg/mL and about 10 mg/mL, into a nasal cavity of the individual, and wherein the therapeutically effective amount of varenicline administered into the nasal cavity is between 5 micrograms and 1000 micrograms.

19. The method of claim 17, wherein the amount of varenicline so administered is between 5 micrograms and 100 micrograms.

26. The method of claim 17, wherein the pharmaceutical formulation comprises a phosphate buffer or a phosphate citrate buffer.

In the ’380 patent, claims 3, 13, and 23:

1. A method of activating a trigeminal nerve in an individual in need thereof comprising administering a therapeutically effective amount of varenicline to the individual, wherein said administration is local administration of a spray of a liquid pharmaceutical formulation comprising a solution of varenicline or a pharmaceutically acceptable varenicline salt and one or more pharmaceutically acceptable inactive ingredients, wherein the concentration of varenicline in the formulation is between about 0.1 mg/mL and about 10 mg/mL, into a nasal cavity of the individual, wherein the therapeutically effective amount of varenicline administered into the nasal cavity is between 5 micrograms and 1000 micrograms.

3. The method of claim 1, wherein the amount of varenicline so administered is between 5 micrograms and 100 micrograms.

> 11. A method of activating an anterior ethmoidal nerve in an individual in need thereof comprising administering a therapeutically effective amount of varenicline to the individual, wherein said administration is local administration of a spray of a liquid pharmaceutical formulation comprising a solution of varenicline or a pharmaceutically acceptable varenicline salt and one or more pharmaceutically acceptable inactive ingredients, wherein the concentration of varenicline in the formulation is between about 0.1 mg/mL and about 10 mg/mL, into a nasal cavity of the individual, wherein the therapeutically effective amount of varenicline administered into the nasal cavity is between 5 micrograms and 1000 micrograms.
>
> 13. The method of claim 11, wherein the amount of varenicline so administered is between 5 micrograms and 100 micrograms.
>
> 21. A method of activating a nasolacrimal reflex in an individual in need thereof comprising administering a therapeutically effective amount of varenicline to the individual, wherein said administration is local administration of a spray of a pharmaceutical formulation comprising a solution of varenicline or a pharmaceutically acceptable varenicline salt and one or more pharmaceutically acceptable inactive ingredients, wherein the concentration of varenicline in the formulation is between about 0.1 mg/mL and about 10 mg/mL, into a nasal cavity of the individual, wherein the therapeutically effective amount of varenicline administered into the nasal cavity is between 5 micrograms and 1000 micrograms.
>
> 23. The method of claim 21, wherein the amount of varenicline so administered is between 5 micrograms and 100 micrograms.

The preambles of all of the claims at issue state that these are method claims, directed to methods of administering varenicline to a person in a therapeutic context. On January 19, 2024, the parties filed a stipulation in which they agreed: "as a matter of claim construction, the preamble of each asserted claim is a limitation of that claim and all claims depending from it . . ." (Docket Entry No. 52.) The Magistrate Judge "So Ordered" that stipulation. (Docket Entry No. 53.) The POSA therefore understands that the term "varenicline" refers to an element administered in a therapeutic context; the claims are directed to methods of using varenicline as a pharmaceutical in a pharmaceutical composition.

In the section titled, "Detailed Description of the Invention," the common specification[2] of the patents at issue contains a subsection, "Intranasal Route of Administration," which begins as follows:

> The methods described herein comprise the local administration of a therapeutically effective amount of a nicotinic acetylcholine receptor agonist into the nasal cavity of an individual in need thereof.

'396 patent, col.66 ll.62-65. The specification states that one such agonist is varenicline. '396 patent, col.64 ll.47-49. This is followed by a subsection titled, "Pharmaceutical Formulations, Methods of Dosing, and Treatment Regimens." '396 patent, col.68 ll.1-2. This subsection defines "pharmaceutical formulation" as follows:

> A pharmaceutical formulation, as used herein, refers to a mixture of a nicotinic acetylcholine receptor agonist as described herein with other chemical components (i.e. pharmaceutically acceptable inactive ingredients) . . .

'396 patent, col.86 ll.41-44. This subsection also states:

> The pharmaceutical formulation facilitates administration of the compound to an organism. In practicing the methods provided herein, therapeutically effective amounts of nicotinic acetylcholine receptor agonist described herein are administered in a pharmaceutical formulation to a mammal having a disease, disorder, or condition to be treated. In some embodiments, the mammal is a human. . . .
>
> The pharmaceutical formulations described herein are administered to the nasal cavity of a subject. . . .
>
> The pharmaceutical compositions will include a nicotinic acetylcholine receptor agonist as described herein as an active ingredient in free-acid or free-base form, or in a pharmaceutically acceptable salt form.

'396 patent, col.87 ll.16-22, 30-31, 38-41. The specification does not differentiate pharmaceutical formulations from pharmaceutical compositions. The claims at issue are directed

[2] The parties agree that all of the patents presently at issue share the same specification.

to methods comprising administering varenicline to an individual for a therapeutic purpose.[3] Varenicline is the active ingredient, the specific nicotinic acetylcholine receptor agonist, which is administered for a therapeutic purpose in the method claims at issue.

The Court observes that the key specification statement declares affirmatively that the "pharmaceutical compositions ***will*** include a nicotinic acetylcholine receptor agonist as described herein as an active ingredient in free-acid or free-base form, or in a pharmaceutically acceptable salt form" (emphasis added). This declaratory statement is unqualified as to which embodiments it characterizes and appears to characterize all the pharmaceutical compositions used in the inventive methods disclosed in all the claims at issue. The specification thus states, affirmatively and clearly, that the pharmaceutical compositions will include an active ingredient (a nicotinic acetylcholine receptor agonist) in either free-base form or pharmaceutically acceptable salt form.

In Phillips, the Federal Circuit summarized the jurisprudence on the role of the specification in claim construction as follows:

> Shortly after the creation of this court, Judge Rich wrote that "the descriptive part of the specification aids in ascertaining the scope and meaning of the claims inasmuch as the words of the claims must be based on the description. The specification is, thus, the primary basis for construing the claims." *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985). On numerous occasions since then, we have reaffirmed that point, stating that "the best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history." *Multiform Dessicants*, 133 F.3d at 1478; *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1360 (Fed. Cir. 2004) ("In most cases, the best source for discerning the proper context of claim terms is the patent specification wherein the patent applicant describes the invention."); *see also, e.g., Kinik Co. v. ITC*, 362 F.3d 1359, 1365 (Fed. Cir. 2004) ("The words of patent claims have the meaning and scope with

[3] The claims at issue provide different statements of the therapeutic purpose of the claimed method: treating dry eye, increasing tear production, activating a trigeminal nerve, activating an anterior ethmoidal nerve, and activating a nasolacrimal reflex. There is no dispute that these methods involve the administration of a pharmaceutical composition.

which they are used in the specification and the prosecution history.").

Phillips, 415 F.3d at 1315. Because the specification is the primary basis for construing the claims, and because the specification clearly states that the pharmaceutical compositions ***will*** include a nicotinic acetylcholine receptor agonist in either free-base form or pharmaceutically acceptable salt form, this Court construes "varenicline" to include both free-base and salt forms.

In a short paragraph, Oyster Point argues that the prosecution history confirms its proposed construction of varenicline, citing statements by the examiner in various office actions. Oyster Point does not, however, explain the basis in Federal Circuit law for relying on the examiner's statements during prosecution. Oyster Point does not point to any relevant statement made by the applicants during prosecution. This Court already discussed the relevant Federal Circuit law in its claim construction opinion dated October 1, 2024, when this Court rejected a similar argument from Apotex: "Statements by the examiner do not constitute intrinsic evidence of the applicants' understanding of the meaning of claim terms." Oyster Point Pharma, Inc. v. Apotex Inc., 2024 U.S. Dist. LEXIS 178954, at *9 (D.N.J. Oct. 1, 2024).

Oyster Point also points to the declaration of Jeffrey Nau, dated December 14, 2023, during prosecution of Application No. 18/125,551. Oyster Point points out that, in this declaration, Nau cited the Wirta reference, a study of "varenicline solution." Oyster Point argues that, in reality, Wirta's "varenicline solution" was varenicline tartrate, and it offers a copy of the Wirta reference, which states that the varenicline solution was "TYRVAYA," without stating what TYRVAYA is. (Miller Dec. Ex. 26 at 380.) Oyster Point's brief claims that TYRVAYA contains varenicline tartrate, but offers no evidence to support the assertion. As a result, Oyster Point's argument based on Nau citing Wirta is incomplete.

In support of its proposed construction, Apotex argues that the intrinsic evidence supports its view that "varenicline" excludes salt forms (as well as ionized forms). Apotex has one argument in support that is based on intrinsic evidence, pointing to claims like claim 1 of the '380 patent, which contains this phrase: "wherein said administration is local administration of a spray of a liquid pharmaceutical formulation comprising a solution of varenicline or a pharmaceutically acceptable varenicline salt." Apotex argues that, if "varenicline" is construed to include its salts, that makes the phrase, "or a pharmaceutically acceptable varenicline salt," superfluous. Apotex points out that it is a canon of Federal Circuit law that constructions that make claim language superfluous are disfavored.

While Apotex is correct about this canon of claim construction, and has made an argument that is colorable, it is nonetheless insufficient to defeat Oyster Point on this issue, because the Federal Circuit has also made clear that, sometimes, this canon must yield to other principles – particularly when the canon and the specification point in conflicting directions. As the Federal Circuit explained:

> Laitram argues that the Board's construction is incorrect because it renders "without slip" superfluous and that "without slip" must have independent meaning because it is not used in all claims that use "positive drive." We find neither argument persuasive. Our preference for avoiding superfluous language is not an inflexible rule—we must still consider all other principles of claim construction, including how a skilled artisan would have understood the term and how it is used in the specification. *SimpleAir, Inc. v. Sony Ericsson Mobile Commc'ns AB*, 820 F.3d 419, 429 (Fed. Cir. 2016). Here, the plain and ordinary meaning of "positively driven" is supported by the specification and reinforced by expert testimony. We decline to use the superfluous language canon to arrive at a conflicting conclusion.

Laitram, LLC v. Ashworth Bros., Inc., 2023 U.S. App. LEXIS 11789, at *9 (Fed. Cir. May 15, 2023); see also SimpleAir, Inc. v. Sony Ericsson Mobile Communs. AB, 820 F.3d 419, 429 (Fed.

Cir. 2016) ("The preference for giving meaning to all terms, however, is not an inflexible rule that supersedes all other principles of claim construction.") Similarly, in the instant case, while this Court acknowledges the "superfluous language" canon of construction, the application of the canon must yield to the statement in the specification in which the applicants unambiguously expressed that the pharmaceutical compositions include agonists in both their free-base form and their salt forms. The Court declines to use the superfluous language canon to arrive at a construction in conflict with the clear statement in the specification.

The specification contains four other references to salt forms of the active ingredient. Three of these references appear in the subsection titled, "Pharmaceutical Formulations, Methods of Dosing, and Treatment Regimens." These three references are similar, containing the introductory phrase, "In some embodiments is a pharmaceutical formulation . . . comprising a nicotinic acetylcholine receptor agonist," followed by "wherein the nicotinic acetylcholine receptor agonist has a structure selected from:," then diagrams of chemical compounds, ending with, "or a pharmaceutically acceptable salt thereof." See, e.g., '396 patent, col.71 l.19-col.72 l.52. Thus, in three places, the specification subsection on pharmaceutical formulations describes embodiments with formulations in which the agonist may be in free-base or salt form. Apotex has pointed to no statements in the specification which disclose a formulation in which the agonist is limited to free-base forms. It appears that the specification does not teach methods of using formulations in which the agonist is limited to a free-base form. This evidence is consistent with Plaintiff's proposed construction, as is the fact that Apotex did not point to anything in the specification that teaches methods of using pharmaceutical formulations in which the agonist is limited to free-base forms.

In conclusion, the Court finds that the specification contains a clear and unqualified statement that the pharmaceutical compositions ***will*** include a nicotinic acetylcholine receptor agonist that is in free-base or salt form. There is no dispute that varenicline is a nicotinic acetylcholine receptor agonist; nor do the parties dispute that the claims at issue are directed to treatment methods involving administering a pharmaceutical composition containing varenicline. The inference arising from application of the "superfluous language" canon of construction is contrary to this clear statement in the specification, and there is no other evidence to support the construction proposed by Apotex. "Varenicline" in the claims at issue includes both its free-base form and its salt form.

SO ORDERED.

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.

Dated: June 24, 2025